

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed April 2, 2008. Claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75, and 80-90 were pending and rejected in view of cited art.¹ Claim 80 has been canceled and claims 11, 21, 27, 32, 40, 47, 60, 63, 68, 73, 81-84 are amended. Claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75, and 81-90 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

B. CLAIM OBJECTIONS

The Office Action objected to claim 80. Claim 80 has been canceled. Applicant respectfully requests removal of this objection.

C. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claims 60-62 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 60 has been amended, in part, to recite "wherein

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

advancing a clip along the selectively expandable locator member until the clip is disposed at a predetermined location relative to the distal portion of the locator member further comprises advancing the clip towards the distal end of the elongate member until tines of the clip penetrate tissue adjacent the body lumen.” Applicant respectfully submits that there is sufficient antecedent basis for amended claim 60 and requests removal of this rejection.

D. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 11-16, 21-25, 27-32, 38-42, 46-49, 51, 54-56, 60-75, and 80-90 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,852,421 (*Leschinsky*) in view of U.S. Patent No. 6,626,918 (*Ginn I*) or U.S. Patent No. 6,391,048 (*Ginn II*), while claim 50 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Leschinsky* in view of *Ginn I* or *Ginn II*, in further view of U.S. Patent No. 5,437,631 (*Janzen*). Applicant respectfully traverses these rejections on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims.

The Office Action asserts that *Leschinsky* “discloses . . . a control element . . . extending along an outer surface of at least the intermediate portion of the helically wound wire” (Office Action, pages 3-4). The Office Action has cited *Leschinsky*’s “wire barb 228” as “a control element” and cited Figure 28 of *Leschinsky* in support of this assertion. Claim 63 recites a “control element . . . extending along an outer surface of at least the intermediate portion of the helically wound wire in a pre-deployed configuration.” Applicant respectfully submits that *Leschinsky* does not teach or suggest this limitation. Specifically, wire barb 228 is not “a control element,” as recited, in part, by claim 63.

Applicant respectfully submits that the embodiment disclosed in Figures 28-37 is different from the embodiment shown in Figures 1-27. Specifically, *Leschinsky* discloses “three basic types of releasable anchors. The first is a loop anchor [shown in Figures 1-27] which is formed by turning the distal tip of the insertion wire back upon itself so as to cross the main body of the wire, with the distal tip then forming a pig tail. The second type of anchor [shown in

² Support for the claim amendments and/or new claims can be found throughout the specification and drawings as originally filed.

Figures 28-37] is formed by use of a soft-tipped barb that protrudes from the insertion wire sheath slightly proximal to the distal end. The third type of releasable anchor [shown in Figures 38-43] according to the present invention is comprised of an elongated overlapping loop at the distal end wherein the overlapping loop sections are comprised of interleaved coils” (*Leschinsky*, col. 3, ll. 15-25).

The Office Action also cited core wires 12 and 212 as “control elements” (Office Action, page 3). Apparently, the Office Action is asserting that core wires 12 and 212 are the same thing as wire barb 228. However, the Office Action has also asserted that core wire sheath 214 is the same as “a locator member” (*Id.*). The releasable anchors generally include a core wire (12, 212, 302) running through a core sheath (14, 214, 304). Thus, the Office Action is mistakenly citing the releasable anchor (wire barb 228) of Figure 28 as a core wire (core wire 212), which does not “extend along an outer surface of at least the intermediate portion of the helically wound wire,” as recited, in part, by claim 63.

Although *Leschinsky* discloses that “sheath [14] may also be formed of a metal coil,” Applicant respectfully submits that core wire 12 does not “extend along an outer surface of at least the intermediate portion of the helically wound wire in a pre-deployed configuration,” as recited, in part, by claim 63. Rather, “[s]heath 14 . . . ha[s] a slit near the distal end” such that “[a]t the slit, the sheath can be caused to buckle or form a bulge or notch 18 leaving a gap 20 between the core wire 12 and the slit portion of the sheath which forms notch 18” (*Leschinsky* col. 7, ll. 41-42 and col. 5, ll. 6-11). Thus, the core wire 12 does not “extend along an outer surface of at least the intermediate portion of the helically wound wire in a pre-deployed configuration,” as recited, in part, by claim 63.

As shown above, *Leschinsky* does not teach or suggest a “control element . . . extending along an outer surface of at least the intermediate portion of the helically wound wire in a pre-deployed configuration,” as recited, in part, by claim 63. Claims, 11, 21, 27, 40, 47, and 68 have been amended to recite “a control element . . . along an outer surface of at least one coil of the helical wound wire and passing through at least one coil of the helical wound wire in a pre-deployed configuration.” Applicant respectfully submits that *Leschinsky* does not teach or suggest this limitation.

In addition, the Office Action has not cited, nor can Applicant find, any portion of *Ginn I*, *Ginn II*, or *Janzen* that discloses, teaches, or suggests these limitations. Rather, *Ginn I* and *Ginn II* were cited as “disclos[ing] that it was known to either supplement a clip closure with a sealant, or that a clip is a known alternative to the use of a sealant in closing vessel puncture wounds” and *Janzen* was cited as “disclos[ing] that introducing one or more instruments through the lumen of the tubular member (32) into the body lumen prior to performing the closure of the blood vessel” (Office Action, pages 8 and 11). Therefore, the Office Action’s proposed combinations of *Leschinsky*, *Ginn I*, *Ginn II*, and *Janzen* do not disclose, teach, or suggest each and every element of independent claims 11, 21, 27, 40, 47, 63, and 68 and dependent claims 12-16, 22-25, 28-32, 38-39, 41-42, 46, 48-51, 54-56, 60-62, 64-67, 69-75, and 81-90. Applicant respectfully requests that the rejections under 35 U.S.C. § 103(a) be withdrawn.

Furthermore, *Leschinsky* teaches away from the use of “a clip,” as recited, in part, by claims 11, 21, 27, 40, 47, 63, and 68. Specifically, *Leschinsky* expressly states that “[t]he invention permits precise and definitive location of the plug adjacent the arterial puncture but outside of the arterial lumen and leaves no foreign body in the lumen when the procedure has been completed” (*Leschinsky*, col. 1, l. 67 through col. 2, l. 3). Applicant respectfully submits that “a clip,” as recited, in part, by the independent claims is a foreign body because it is not naturally occurring in a body lumen. Therefore, *Leschinsky* expressly states that an intended purpose of the invention of *Leschinsky* is to “permit[] precise and definitive location of the plug . . . [without] leav[ing a] . . . foreign body in the lumen.” Thus, *Leschinsky* teaches away from the use of a clip disclosed by *Ginn I* and *Ginn II* or any other clip reference because the use of a clip would render *Leschinsky* inoperable for its intended purpose.

E. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the

future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds and remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 2nd day of October, 2008.

Respectfully submitted,

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